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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-------------|----------------------|---------------------|------------------|
| 10/632,064 | 07/31/2003 | Matthias Schiell | DEAV2002/0061 US NP | 3761 |
| 5487 | 7590 | 01/24/2005 | EXAMINER | |
| | | | SHIAO, REI TSANG | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1626 | |
| DATE MAILED: 01/24/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/632,064 | SCHIELL ET AL. | |
| | Examiner | Art Unit | |
| | Robert Shiao | 1626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on application filed on 07/31/2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-9 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>10/24/03, 1/12/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. This application claims priority of the foreign application:

GERMANY 10236262.9 with a filing date 08/07/2002.

2. Claims 1-9 are pending in the application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It is noted that the claims contains subject matter "oxime functions", "amide functions", and "or prophylaxis", which were not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, i.e., see claim 1, page 19, lines 3-4, or claim 7, line 1.

4. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating bacterial infection using a compound of formula (I), wherein alkyl of the variable R³ is substituted with amide or oxime, does not reasonably provide enablement a method of preventing (i.e.,

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prophylaxis) bacterial infection using a compound of formula (I), wherein alkyl of the variable R³ is substituted with amide or oxime, and the amide or oxime have a morpholine moiety, see pages 1-4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1988):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention

The claims are drawn to a compound of formula (I) without limitation of "amide functions", "oxime functions", and its methods of use "preventing bacterial infection".

2) State of the prior art

The reference Holton et al. US 5,284,864 does not indicate which compounds of instant compounds may be useful in the claimed invention. Holton et al. '864 is

pertaining to butenyl substituted taxanes and pharmaceutical compositions containing them.

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. The claims are drawn to “a compound of formula (I) without limitation of “amide functions”, “oxime functions”, and its methods of use “preventing bacterial infection””. Applicant’s specification does not enable the public to prepare such “a compound of formula (I) without limitation of “amide functions”, “oxime functions”, and its methods of use “preventing bacterial infection”” by the instant examples disclosed in the specification.

4) Level of predictability in the art.

The claims are drawn to “a compound of formula (I) without limitation of “amide functions”, “oxime functions”, and its methods of use “preventing bacterial infection””, see claim 1, page 19, lines 3-4, or claim 7, line 1. Different types of the genus of compounds or methods require various experimental procedures and without guidance that is applicable to all possible “see claim 1, page 19, lines 3-4, or claim 7, line 1, there would be little predictability in the scope of claimed compounds or methods.

5) Amount of direction and guidance provided by the inventor.

The claims are drawn to “a compound of formula (I) without limitation of “amide functions”, “oxime functions”, and its methods of use “preventing bacterial infection””, encompasses a vast number of compounds or methods. Applicant’s limited guidance does not enable the public to prepare such “a compound of formula (I) without limitation of “amide functions”, “oxime functions”, and its methods of use “preventing

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bacterial infection"" in the specification. There is no enablement for "a compound of formula (I) without limitation of "amide functions", "oxime functions", and its methods of use "preventing bacterial infection", i.e., amide or oxime has a morpholine moiety, preventing any bacterial infection, which are neither enabled nor supported in the specification.

6) Existence of working examples.

The claims are drawn to "a compound of formula (I) without limitation of "amide functions", "oxime functions", and its methods of use "preventing bacterial infection", encompasses a vast number of compounds or methods. Applicant's limited working examples do not enable the public to prepare such a numerous amount of "a compound of formula (I) without limitation of "amide functions", "oxime functions", and its methods of use "preventing bacterial infection"" in the specification. Applicants claim "a compound of formula (I) without limitation of "amide functions", "oxime functions", and its methods of use "preventing bacterial infection""", however, the specification provides only limited examples of the compounds or methods.

7) Breadth of claims.

The claims are extremely broad due to the vast number of possible "a compound of formula (I) without limitation of "amide functions", "oxime functions", and its methods of use "preventing bacterial infection"".

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In

particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The skilled artisan would have a numerous methods in order to obtain “a method of minimizing impurities without limitation” as claimed. Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed compounds without undue experimentation, see *In re Armbruster* 185 USPQ 152 CCPA 1975. Incorporation of the limitation of “amide functions” and “oxime functions” of the compound of formula (I), and elimination the limitation “or prophylaxis” of claim 7, would obviate the rejection, see pages 1-4 of the specification.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, recites the limitation “amide functions” and “oxime functions”, is ambiguous and indefinite. It is unclear what “amide functions” or “oxime functions” is. Clarification is required, see pages 1-4, and Examples 1-6 on pages 12-16.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707.

The examiner can normally be reached on 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

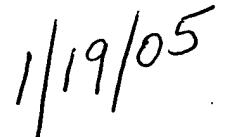
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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1/19/05

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